



K101439

FEB - 7 2011

510(k) Summary

807.92(c)

1 Submitter Information:

807.92(a)(1)

1.1 Submitter:

Codonics, Inc.
17991 Englewood Drive
Middleburg Heights, Ohio 44130

1.2 Manufacturing Facility:

Same as above

1.3 Representative:

Not applicable at this time

1.4 Contact:

Gary W. Enos, Phone: (440) 243-1198 / Fax : (440) 243-1334
17991 Englewood Drive
Middleburg Heights, Ohio 44130

1.5 Date: February 1, 2011

2 Device Name

807.92(a)(2) & 807.92(a)(3)

2.1 Anesthesia Devices: Therapeutic Devices: Accessories

2.2 Classification Name: Gas machine for anesthesia or analgesia, Accessory

Classification Number: 868.5160

2.3 Classification Code: BSZ

2.4 Trade/Proprietary Name: Codonics Safe Labeling System

Included Products: Codonics Safe Labeling Software & Standalone Center
Codonics Safe Labeling System Family (Integrated)
Codonics Safe Labeling (SLS XXX)
Multiple Models Pending Configuration

2.5 Predicate/Comparative Devices: 807.92(a)(3)

Codonics has identified Medley System with Bar Code Module (Pre-market notification K041241) and the SAFERsleep System (Pre-market notification K050883) and DocuSys Digital Drug Management (Pre-market notification K062388) and Philips CompuRecord Perioperative System (Pre-market notification K030939).

3 Device Description

807.92(a)(4)

3.1 Function

Drug preparation and administration in the perioperative environment are integral aspects of anesthesiologist's patient care responsibilities.

Codonics Safe Labeling System is a simple, integrated system utilizing a bar code scanner to read and confirm drug identity from NDC and other drug ID Barcodes from vials automatically print labels for prepared drugs and other items in use on patients during surgical procedures. The labels are compliant with national regulations focused on improving medication safety in the perioperative environment.

The software components provide functions for scanning vials, creating, indexing, and approved hospital managed promotion of a formulary database, displaying on screen and audibly confirming drug type, printing color The Joint Commission ISO and ASTM compliant labels with 2-D barcodes. The system reads drug vial barcodes and produces waterproof, color labels.

The system can be integrated to function with AIMS system workflow to provide real-time documentation of drug administration when the syringe "2D Barcode" is read.

- 3.2 **Scientific Concepts:** NDC or UDI barcodes are read from drug vials and compared to an formulary of drugs approved for use by the hospital pharmacy. The formulary contains drug name, concentration, expiration, site specific warnings, dilutions and class of drug templates (for color and pattern label production). Once identified and confirmed, a vial label is displayed along with audible indication of the drug scanned. Specific site directed rules for approved conditions of use are promoted to each SLS. When vials scanned are not found in the database, a "Drug not found" indication is made and the user is warned and prompted to produce a manual label.

3.3 Physical And Performance Characteristics:

Codonics Safe Labeling System consists of :

- PC (x86 Pico-ITX based w/on-board RAM) with Ethernet interface
- SSD/Flash disk
- Touch screen end-user interface (for configuring and controlling authorized users, barcode scan and print jobs, selection of label type and manual/automatic label production % dilution factor indication)
- Barcode scanner/decoder
- Label printing engine
- Medical grade (EN60601-1) compliant power supply

Software to support primary functions:

- Linux OS for CPU, I/O (USB, IDE or SATA, AUDIO, Network (Ethernet/WIFI), SSD Disk access, and Touch Screen LCD display
 - Specific Drivers for Touch Screen LCD, Ink Jet label printer, Barcode scanner, Ethernet/WIFI communications
 - NDC or other UDI (Unique Drug Identifier, commonly known in the US as an "NDC") drug formulary persistent repository (or database) via SSD/USB Flash
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In addition to these primary functions, there are other functions that are provided by the software, to include:

- System configuration (network, security, profiles, etc.)
- Security management to perform accounting and authentication of user data; add users to the User Database when requested and verify that any authenticating user credentials are correct
- Settings management global component available to all other components in the application; lookup configuration values given the appropriate configuration key
- User feedback (job and device status, errors, etc.) various events that describe the current state of the system are generated
- Job function application *managers*. Each manager is responsible for a specific set of functionality grouped by a logical theme. For example, the Label Manager handles creating labels based on a set of Label Parameters, the Security Manager handles all issues relating to user management and authentication, and the Print Manager sends commands to and receives responses from the printer hardware

Software Application Description: The software scans user Identification (authentication) and drugs by means of a bar code, and identifies connected devices (printers, computer, and barcode scanner, etc.). The software allows a label to be printed which has a color or colors identifying the type of drug contained in the syringe, the name of the drug or drugs, the units of the drug or drugs, the amount of the drug or drugs, total volume of the syringe, the user ID of the preparer, the time and date of the preparation, and a bar code identifying the contents of the syringe. The software also enables the clinician to document the administration of the drug or drugs by reading the bar code printed on the label and transmitting the drug identification to a third party application (i.e. AIMS system). The system also allows for the labeling of drugs which are combined with other drugs or are diluted. Finally, the software also allows the printing of blank labels, with just the clinician's ID and the data/time.

The major characteristics and functions of the family of devices include:

- Scanning the FDA required drug vial barcode directly from the vial
 - Decoding the manufacturer issued barcode into the required FDA national drug code (NDC) or Unique Drug Identifier (UDI) number
 - Referring the NDC/UDI number to a site managed formulary lookup database
 - Providing audio and ISO-compliant visual "readback" of the drug name
 - Providing a clinical alert if the drug vial is listed as recalled in the site formulary
 - Printing an easy to read, waterproof ISO 26825 compliant color label meeting The Joint Commission medication management standards and the American Society of Anesthesiologists guidelines for labeling
 - Including on same label a printed barcode compliant with national standards for machine readability allowing integration with an anesthesia information management system (AIMS)
 - Providing the basic information by which the printed label barcode can be read to document medication administration in an AIMS system
 - Providing a 2D barcode of information to permit integration with AIMS systems with potential for alerts if the prepared drug has expired based on preparation time and site specific drug use criteria
 - Printing labels with insertion and expiration date and time for IV lines
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4 Device Intended Use: 807.92(a)(5)

- 4.1 The Codonics Safe Label System (SLS) and SLS Software provides a simple computer-based bar code scanning & printing system to automatically verify drug identity from NDC and other drug vial UDI Barcodes, and to print labels for prepared drugs and other items in use on patients during surgical procedures. An integrated formulary database reliably confirms vial barcodes with both audible and visual display of the drug name and concentration. The SLS system produces waterproof, ASA compliant color labels per ISO and ASTM standards. The software components provide the functions for scanning vials, indexing against a hospital managed formulary database, displaying on screen and audibly confirming drug type, and printing color The Joint Commission compliant labels with 2-D barcodes.
- 4.2 The use of drug class specific pattern and color per ASTM D4774 and ISO 28625 Specifications for User Applied Drug Labels in Anesthesiology is configurable by site and "Data-set". Data-sets are uniquely named configurations that may differ in drugs, colors, dilutions and comments to accommodate different practices within a single site or hospital (pediatric versus cardiac for example).
- 4.3 Additional uses include producing labels for IVs and other artifacts used during a surgical procedure.
- 4.4 Codonics Safe Label System (SLS) is generally placed in, however not limited to, the peri-operative environment to identify syringes prepared for anesthesiology use during surgery..
- 4.5 Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians
- 4.6 Barcode scanning with SLS formulary confirmation of drug, expiration, and suitability is equivalent to the predicate devices employing similar technology. Labeling or identification of the syringe with input to AIMS system in the process of patient surgical care is equivalent in technology to previously cleared devices employing similar technology.
- 4.7 510(k) Indications for Use Statement: Prescription Use Device**

The Codonics Safe Label System (SLS) and SLS Software provides a simple computer-based bar code scanning & printing system to automatically verify drug identity from NDC and other drug vial UDI Barcodes, and to print labels for prepared drugs and other items in use on patients during surgical procedures.

Codonics Safe Label System (SLS) is generally placed in, however not limited to, the peri-operative environment to identify syringes prepared for anesthesiology use during surgery. Additional uses include producing labels for IVs and other artifacts used during a surgical procedure. SLS can also be used to print "non-surgical environment" color & text labels as required. Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians

5 Device Technological Characteristics: 807.92(a)(6)

- 5.1 The Codonics Safe Label System is a new device in terms of a product demonstrating the same completely integrated functionality. The SLS device does employ substantially equivalent technology with respect to reading bar codes as the **Medley System with Bar Code Module (Pre-market notification K041241)** and the **SAFERsleep System (Pre-market notification K050883)** with visual and auditory feed back confirmation. The SLS system also employs equivalent technology as **DocuSys Digital Drug Management (Pre-**
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market notification K062388) and Philips CompuRecord Perioperative System (Pre-market notification K030939) in terms of barcode read information reference with a drug formulary list/database and claims of similar system function and intended uses.

- 5.2 The technology and applications are substantially equivalent to these products already cleared to market by the FDA with respect to drug identification, alert management and in the ability to record/input the time and type of drug administration during surgery via labeling barcodes read by AIMS (Anesthesia Management Systems).
- 5.3 The software components provide functions for scanning vials, indexing against a hospital managed formulary database, displaying on screen and audibly confirming drug type with printing color compliant labels with 2-D barcodes. End-user feedback and confirmation improves the safety and effectiveness of the device when used as labeled. .
- 5.4 The system integration with AIMS can provide real-time documentation of drug administration.

6 Testing and Equivalence: 807.92(b)(1), 807.92(b)(2) & 807.92(b)(3)

- 6.1 In the code implementation, electrical compliance tests, simulation, Bar code reading, UDI/NDC confirmation, NPSG.03.04.01 Labeling, and clinical operations, results and outcomes have been thoroughly reviewed with proper operation and intended functions verified. Both laboratory (non-clinical environment) and surgical (clinical) tests have shown error free NDC/UDI vial reading and labeling of prepared drugs to ASA/ISO standards.
- 6.2 The non-clinical lab tests were conducted utilizing NDC/UDI codes vials scanned and compared to the output of the MGH original SafeLabels system is referenced in the original K101439 submission Attachment 6, Tab 11 and documented in Attachment 5, Tab 8..
- 6.3 The clinical application of the prototype Safe Label system at MGH is referenced in the original K101439 submission Attachment 6, Tab 11 and documented in Attachment 5, Tab 8.
- 6.4 The production ready device has been designed under ISO 13485 certified controls and has passed the series of electrical safety tests including:

Additional Information Reasonably Deemed Necessary to access safe and effective use
807.92(d)

Emissions

FCC Part 15.109 Class B Radiated Emissions
FCC Part 15.107 Class B Conducted Emissions

Safety

ETL/UL 60601-1 UL or associated lab to test for USA, Canada and various international regional requirements

The subject device has no patient contact however has been designed to meet patient contact (EN60601-1) and anesthesia environment (EN60601-2) electrical safety. The device family does not control, monitor or otherwise affect any devices directly connected to or affecting the patient. Medical personnel review the results and inputs processed by the Codonics SLS and offers ample opportunity for competent human intervention in the case of a malfunction or other failure.

Quality System

QSR compliance to 21 CFR Part 820

Laboratory and preliminary tests have documented effective application, throughput, reliability, and expected results consistent with predicate devices currently in commercial distribution and additional verification and validation testing is planned prior to release.

The SLS device employs substantially equivalent technology with respect to reading bar codes as the **Medley System with Bar Code Module (Pre-market notification K041241)** and the **SAFERsleep System (Pre-market notification K050883)** with visual and auditory feed back confirmation. The SLS system also employs equivalent technology as **DocuSys Digital Drug Management (Pre-market notification K062388)** and **Philips CompuRecord Perioperative System (Pre-market notification K030939)** in terms of barcode read information reference with a drug formulary list/database and claims of similar system function and intended uses.

The technology and applications are substantially equivalent to these products already cleared to market by the FDA with respect to drug identification, alert management and in the ability to record/input the time and type of drug administration during surgery via labeling barcodes read by AIMS (Anesthesia Management Systems). Attachment 8 of the original K101439 submission contains information describing these predicate devices and provides a comparison of the Codonics Safe Label System (SLS) technology to the predicate device(s) and describes how any differences of note are substantially equivalent.

APPLICABLE PERFORMANCE STANDARDS: Codonics has designed the Safe Labeling System to comply with the following standards:

6.5 Recognized Consensus Standards With respect to prepared drug labeling & devices

- **ASTM D4774 - 06** Standard Specification for User Applied Drug Labels in Anesthesiology: size, color and pattern, and type used on labels applied to unlabeled syringes filled by the users or their agents to identify the drug content. Not intended to cover labels applied by the drug manufacturer.
 - **ISO 26825:2008** Anesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anesthesia – Color, design and performance
 - **ASTM D4267**, Standard Specification for Labels for Small-Volume (100 ml or less) Parenteral Drug Containers: contrast; label; label content; legibility; legibility test; parenteral drug; type size applied to unlabeled volumes filled by the users or their agents to identify the drug content
 - **ASTM D6398**, Standard Practice to Enhance Identification of Drug Names on Labels: covers the shape, size, color, layout, typeface, and bar-coding practices, use of TALLMAN lettering
 - **National Drug Code (NDC) number (21 CFR 201.25)**, Bar Code Recognition
 - **Joint Commission on Accreditation of Healthcare Organizations NPSG. 03.03.01, 03.04.01, and 03.05.01** Re: Enhanced ID of Look Alike/Sound Alike Drugs, Labeling all medications, syringes, medication containers, and other solutions on and off the-sterile field in perioperative and other procedural settings, ID for increased safety of anticoagulant preparations
 - **ISMP** -The Institute for Safe Medication Practices and the **FDA-U.S. Food and Drug Administration Look-Alike Drug Name Sets With Recommended Tall Man Letters**
 - **ASA GUIDE ON LABELING OF PHARMACEUTICALS FOR USE IN ANESTHESIOLOGY**
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- **IEC 60601-1, 60601-1-2 and 61000:** Medical electrical equipment standards (electrical safety, emissions).

7 Hazard Analysis and Safety Concerns

- 7.1) Codonics initially determined the **Software Level of Concern** of this device to be **Major** based on: the software functions and intended use in combination with a drug or biologic.
- 7.2) Codonics considered the risks to be mitigated that could result in potential human injury if wrong drug as labeled is administered:
- a- misreading of barcode
 - b- failure to database index proper drug
 - c- failure to visibly or audibly validate the drug
 - d- failure to print the correct color label and/or drug identification on label
 - e- failure to present the correct barcode.
- 7.3) Hazard analysis on this product has been performed throughout the product concept and testing phases of the product development and implementation. This process has emphasized:
- Identification of potential hazards, their causes and their effects
 - Development of methodologies to control the occurrence of hazards and to constrain their effects;
 - Determine any effect on patient safety and system effectiveness
 - The FMEA Electrical, Software and Supplemental System Actions to mitigate potential risks have been completed with action taken described as part of the FMEA forms submitted

The potential hazards associated with this product are not different than those of other devices in this category. These are primarily related to the failure of computer system components, and may be variously obviated by decisions taken by the end users of the product. None of the failures are expected to materially contribute to patient death or injury.

It is our conclusion that there is no hardware or software component, operating in a properly configured environment, whose latent design defect would be expected to result in death or injury of the patient. Thus the "**level of Concern**" is **reduced to "Moderate" in the production ready 1.0.0 version device.**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Gary W. Enos
VP, Business and Technology Integration
Codonics, Incorporated
17991 Englewood Drive
Middleburg Heights, Ohio 44130

FEB - 7 2011

Re: K101439
Trade/Device Name: Codonics Safe Label System (SLS)
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: February 1, 2011
Received: February 3, 2011

Dear Mr. Enos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101439

Device Name: Codonics Safe Label System (SLS)

Included Products: Codonics Safe Label System
Models: Codonics Safe Labeling System (Integrated)
Codonics Safe Labeling Software & Standalone Center
Codonics Safe Labeling (SLS XXX)
Multiple Models Pending Configuration
(exact model number to be determined)

Indications for Use:

The Codonics Safe Label System (SLS) and SLS Software provides a simple computer-based bar code scanning & printing system to automatically verify drug identity from NDC and other drug vial UDI Barcodes, and to print labels for prepared drugs and other items in use on patients during surgical procedures.

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Prescription Use X

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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